

AMENDED IN ASSEMBLY MAY 3, 2000

CALIFORNIA LEGISLATURE—1999–2000 REGULAR SESSION

ASSEMBLY BILL

No. 2832

Introduced by Assembly Member Alquist

February 28, 2000

An act to amend Section 111655 of the Health and Safety Code, relating to health.

LEGISLATIVE COUNSEL'S DIGEST

AB 2832, as amended, Alquist. ~~Licensing—investigational drugs~~ *Investigational devices: licensure: exemption.*

Existing law, the Sherman Food, Drug, and Cosmetic Law, contains various provisions regarding the packaging, labeling, and advertising of food, drugs, and cosmetics.

That law prohibits any person from manufacturing any drug or device in the state unless he or she has a valid license from the State Department of Health Services.

This bill would exempt from those licensing requirements any *person who manufactures any* device intended solely for investigational use by experts to investigate the safety and effectiveness of drugs or devices that meet certain regulatory requirements.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: no.

The people of the State of California do enact as follows:

SECTION 1. Section 111655 of the Health and Safety Code is amended to read:

111655. The licensing provisions of this chapter shall not apply to any of the following:

(a) Any pharmacy that maintains establishments in conformance with provisions of the Pharmacy Law, Chapter 9 (commencing with Section 4000) of Division 2 of the Business and Professions Code, regulating the practice of pharmacy, and that is regularly engaged in dispensing prescription drugs or devices, upon prescriptions of any person licensed to administer the drugs or devices to patients under the care of the person in the course of his or her professional practice, and that does not manufacture, prepare, propagate, compound, or process drugs or devices for sale other than in the regular course of his or her business of dispensing or selling drugs or devices at retail.

(b) Any pharmacy that solely engages in providing drugs or devices to a person licensed by law to administer the drug or device for his or her use in the course of his or her professional practice.

(c) Any pharmacy that solely provides drugs or devices to another pharmacy in order to meet a temporary inventory shortage.

(d) Any person who is licensed by law to prescribe or administer drugs or devices and who manufactures, prepares, propagates, compounds, or processes drugs or devices solely for use in the course of his or her professional practice.

(e) Any person who manufactures, prepares, propagates, compounds, or processes any drug or device solely for use in nonclinical research, teaching, or chemical analysis and not for sale.

(f) Any wholesaler, as defined in Section 4038 of the Business and Professions Code.

(g) Any such other class of persons as the department may by regulation exempt from the application of this article upon a finding that licensing by a class of persons

1 in accordance with this article is not necessary for the
2 protection of the public health.

3 (h) Any registered dispensing optician licensed
4 pursuant to the provisions of Chapter 5.5 (commencing
5 with Section 2550) of Division 2 of the Business and
6 Professions Code, who is regularly engaged in dispensing
7 or selling prescription lenses and frames, and not engaged
8 in the manufacture, preparation, processing or
9 assembling of lenses or frames for sale other than in the
10 regular course of his or her business of dispensing or
11 selling lenses or frames at retail.

12 (i) Any *person who manufactures any* device
13 intended solely for investigational use by experts
14 qualified by scientific training and experience to
15 investigate the safety and effectiveness of drugs or
16 devices, and ~~which~~ *that* is manufactured and used in
17 compliance with all applicable United States laws and
18 regulations, and ~~which~~ *that* is manufactured and used in
19 compliance with the law of the host country, if the device
20 is intended for use outside the United States.

